K073055

510(k) Summary of Safety and Effectiveness for the Dimension® Enzymatic Creatinine (ECRE) Flex® Reagent Cartridge (DF270)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: _____

B. Date of Preparation: October 24, 2007

JAN - 3 2008

C. Proprietary and Established Names:

Dimension® Enzymatic Creatinine (ECRE) Flex® Reagent Cartridge (DF270)

D. Applicant:

Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Regulatory Information:

1. Regulation section: 21 CFR § 862.1225 Creatinine Test System
2. Classification: Class II
3. Product Code: JFY – Enzymatic Method, Creatinine
4. Panel: Clinical Chemistry

F. Predicate Device:

The Dimension® ECRE Flex® reagent cartridge is substantially equivalent to Roche's Creatinine Plus Reagent (K003261).

G. Device Description:

The Dimension® ECRE Flex® reagent cartridge is a prepackaged *in-vitro* diagnostic test method that is specifically designed to be used on the Dade Behring Dimension® Clinical Chemistry System. The reagents contained in the Dimension® ECRE Flex® reagent cartridge are: Reagent 1 – TAPS buffer, creatinase, sarcosine oxidase, HTIB; Reagent 2 - TAPS buffer, creatininase, horseradish peroxidase, 4-aminophenazon, and potassium hexacyanoferrate (II).

H. Intended Use: The ECRE method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma, and urine on the Dimension® clinical chemistry system. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for other urine analytes.

I. Substantial Equivalence Information:

The Dimension® ECRE Flex® reagent cartridge and the predicate, Roche Creatinine Plus reagent were compared. A comparison of the important similarities and differences between the device and the predicates is provided in the following table:

Feature	Dimension® ECRE Flex® reagent cartridge	Creatinine Plus Reagent (K003261)
Intended Use	The ECRE method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma, and urine on the Dimension® clinical chemistry system. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for other urine analytes.	Enzymatic in vitro assay for the direct quantitative determination of creatinine in human serum, plasma and urine using Roche clinical chemistry analyzers.
Sample Type	Plasma, serum, and urine.	Human serum, plasma and urine.
Measuring Range	0.03 -20.00 mg/dL	0.03 – 30 mg/dL
Sample Size	6 µL	6 µL
Measurement	Bichromatic end point	Bichromatic end point

J. Conclusion:

The Dimension® ECRE Flex® reagent cartridge is substantially equivalent to Roche's Creatinine Plus Reagent (K003261). Comparative testing described in the protocol included in this submission demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 3 2008

Dade Behring, Inc.
Glasgow Business Community
c/o Mr. Victor Carrio
RA/QS Compliance Manager
P.O. Box 6101, M/S 514
Newark, DE 19714-6101

Re: k073055
Trade/Device Name: Dimension Enzymatic Creatinine (ECRE) Flex Reagent Cartridge, Model DF270
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system.
Regulatory Class: Class II
Product Code: JFY
Dated: October 29, 2007
Received: October 30, 2007

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known):

Device Name:

Dimension® ECRE Flex® Reagent Cartridge (DF270)

Indications for Use:

The ECRE method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma, and urine on the Dimension® clinical chemistry system. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for other urine analytes.

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K073055

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)